## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

re Application of:	) Art Unit: 1647
NIELSEN, et al.	Examiner: DEBERRY, R.
Serial No.: 09/845,717	) Washington, D.C.
Filed: May 2, 2001	) September 20, 2004
For: METHODS FOR TREATMENT OF DISEASES ASSOCIATED WITH	) Docket No.: NIELSEN=3B
INFLAMMATION	Confirmation No.: 3818

## FOURTH INFORMATION DISCLOSURE STATEMENT [IDS]

U.S. Patent and Trademark Office 2011 South Clark Place Customer Window Crystal Plaza Two, Lobby, Room 1B03 Arlington, Virginia 22202

## Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

- 1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:
- [] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application. See 37 CFR 1.97(b)(1) and (3).
- [ ] B. before the mailing date of a first office action on the merits. See 37 CFR 1.97(b).
- [X] C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below). See 37 CFR 1.97(c)(2).
  - [] i. Counsel certifies that, upon information and belief, each item of information listed herein was

- either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- [X] ii. Credit Card Payment Form, PTO-2038, authorizing payment for the fee set forth in 1.17(p), presently believed to be \$180, is attached.
- [] D. after (A), (B) and (C) above, but before payment of the issue fee. Applicant petitions under 37 C.F.R. 1.97(d) for consideration of this IDS. A Credit Card Payment Form, PTO-2038, authorizing payment for the fee set forth in 1.17(p)(1), presently believed to be \$180 is attached. Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- [] E. As a submission in accordance with the transitional procedure for limited examination after final rejection pursuant to 37 CFR §1.129(a). Pursuant to MPEP §706.07(g), page 700-66, col. 2 (August 2001), this IDS is treated as if filed with a period set forth in 37 CFR §1.97(b) and considered without the petition and petition fee required by 1.97(d).
- [ ] F. As a submission with or after a request for continued examination under CFR §1.114, and before the mailing of a first office action on the RCE. See 37 CFR §1.97(b) (4).
- 2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO-1449) of all patents, publications, or other

information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document is attached, except as explained below.

- [] While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged"). Counsel has used a list provided to him by Applicants, and not transferred the information to a PTO-1449, to avoid the risk of any inadvertent error in transferring the information.
- [] A. Documents \_\_\_\_\_ are deemed substantially cumulative to documents \_\_\_\_\_, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- [] B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

[insert serial number/filing date]

Applicants identify these documents by attaching hereto copies of the form PTO-892s and PTO-1449s from the files of the prior applications or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application. If copies of any of these documents cannot be found in the files of the prior applications, the Examiner is requested to so notify counsel before taking action in this case, so replacement copies can be submitted. While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is

"encouraged") and no prohibition on submitting a copy of a form
PTO-1449 or form PTO-892 from a prior case. Indeed, the re-use
of such forms is desirable as it avoids error in transferring the
information, and evidences that the reference was considered in
a prior application. A previously accepted PTO-1449, or an
examiner-prepared PTO-892, necessarily complies with §1.98(b).
[ ] C. Document(s) is (are) U.S.
patent(s) and/or published application(s). As this is a U.S.
application filed after June 30, 2003, or an entry into national
stage under 35 USC §371 after June 30, 2003, the requirement to
file copies of such U.S. patents or published applications has
been waived. (Office of Patent Legal Administration - Pre O.G.
Notice of July 11, 2003).
[X] 3. Documents <u>DE and DI</u> are not in the English
language. In accordance with 1.98(a)(3), Applicants state:
[X] document <u>DE</u> already contain an English language
abstract, summary or claim set.
[ ] a publicly available abstract is attached to each of
documents, and the source of each abstract is
indicated thereon.
[X] document <u>DI</u> is a patent or published patent
application for which counterpart English language
patents or patent applications exist, and are enclosed,
as follows:
Foreign Lang. Doc.# English Lang. Doc.#
EP 0 972 522 USP 5,028,592
[ ] applicants have prepared an English translation of at
least the pertinent portions of documents,
and copies are attached.
[ ] A concise explanation of the relevance of documents
is found in the attached search report from
the Patent Office (see reply to Comment 68 in

the preamble to the final rules; 1135 OG 13 at 20).
[ ] A concise explanation of the relevance of documents

\_\_\_\_\_ is set forth as follows:

[Insert concise explanation of relevance]

- 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).
- 5. If the month of publication of a nonpatent reference is not stated, it is because it is not apparent from review of the reference. If requested to do so by the Examiner, Applicants will attempt to locate and write to the publisher.

If the publication date of a cited document is set forth only as a publication year, and that year is prior to the year of filing or, if priority is claimed, year of priority of this application, then the particular month of publication is not in issue. Likewise if that publication year is after the year of filing of this application, the month of publication is not in issue.

If the date of publication of a nonpatent reference is stated, then, except as explained below, it is the nominal date stated in the reference, or in a larger document (journal or book) from which the reference was extracted. Applicants reserve the right to challenge this date by contacting the publisher to determine the actual shipment date, or by contacting recipients to determine the receipt dates.

6. Other information being provided for the examiner's consideration follows:

[insert other information]

7. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

## USSN - 09/845,717

8. The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this paper or credit any overpayment to Deposit Account No. 02-4035.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.

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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE									ATTY DOCKE	T NO: NIELSEN=3B	SERIAL NO: 09/845,717			
LIST OF DOCUMENTS CETTED BY									APPLICANT: NIELSEN, et al.					
SEP 2 0 2004 55										FILING DATE: May 2, 2001 GROUP: 1647				
U.S. PATENT ROCUMENTS include at least patentee, patent number and issue date)														
EXAMINER INITIAL		DOCUMENT NUMBER							DATE	PATENTEE	CLASS	SUB- CLASS	FILING DATE IF APPROP.	
3	DA	5	0	2	8	5	9	2	02JUL1991	LIPTON	<u> </u>			
	DB	5	7	3	1	4	0	8	24MAR1998	HADLEY, et al.				
	DC	5	8	3	0	9	9	4	03NOV1998	D'HINTERLAND				
FOREIGN PATENT DOCUMENTS (include at least document number, publication date and country)														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES/NO	
	DD	8	7	0	4	6	2	3	13AUG1987	WIPO			YES	
	DE	9	6	4	1	8	1	5	27DEC1996	WIPO	<u> </u>		YES	
	DF	9	9	2	1	5	7	1	06MAY1999	WIPO			YES	
•	DG	9	9	5	7	1	4	8	11NOV1999	WIPO	_		YES	
	DH	0	3	1	7	5	7	3	22APR1992	EPC			YES	
•	DI	0	9	7	2	5	2	2	19JAN2000	EPC	<u> </u>		YES	
	OTHER DOCUMENTS (include author, title, name of publication, volume, pages & date of publication)													
	DJ	ex	OOSTENBRINK, et al., "Resource use and risk factors in high-cost exacerbations of COPB", Respiratory Medicine, vol. 98, pp. 883-891, 2004.											
	DK	Ex	SAETTA, et al., "Airway Eosinophilia in Chronic Bronchitis during Exacerbations", Am. J. Respir. Crit. Care Med., vol. 150, pp. 1646-1652, 1994.											
	DL	WI Ph	WIKBERG, et al., "New Aspects on the Melanocortins and their Receptors", Pharmacological Research, vol. 42, no. 5, pp. 393-420, 2000.											
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EXAMINER								_		DATE CONSIDERED				
<b>EXAMINER:</b> Initial if reference considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														